PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

2 DEC 2004

Applicant's or agent's file reference 2402PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU2003/000898	International Filing Date *(day/month/year)* 11 July 2003	Priority Date *(day/month/year)* 12 July 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl.[7] C07K 14/47, 14/475, 14/65; C07H 21/04; A61K 38/17, 38/18, 38/30; A61P 35/00		
Applicant THE UNIVERSITY OF ADELAIDE et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheet(s).

3. This report contains indications relating to the following items:

   - I [X] Basis of the report
   - II [ ] Priority
   - III [ ] Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV [ ] Lack of unity of invention
   - V [X] Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI [ ] Certain documents cited
   - VII [ ] Certain defects in the international application
   - VIII [ ] Certain observations on the international application

Date of submission of the demand	Date of completion of the report
19 January 2004	26 February 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer G THOMPSON Telephone No. (02) 6283 2240

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU2003/000898

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed.

☒ the description, pages **1-25** as originally filed,
pages , filed with the demand,
pages , received on with the letter of

☒ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages **26-30** received on **19 January 2004** with the letter of **19 January 2004**

☒ the drawings, pages **1/6-6/6** as originally filed,
pages , filed with the demand,
pages , received on with the letter of

☒ the sequence listing part of the description:
pages **1/4-4/4** as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☒ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims 1-39	YES
	Claims	NO
Inventive step (IS)	Claims 1-39	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-39	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

NOVELTY (N) AND INVENTIVE STEP (IS) Claims 1-39 ACKNOWLEDGED

Journal of biotechnology, Vol. 61, 1998, Lucic, M. et al, "Secretion in Escherichia coli and phage display of recombinant insulin-like growth factor binding protein-2" pp. 95-108

Journal of Molecular Endocrinology, Vol. 23, 1999, Bramani S. et al., "Amino acids within the extracellular matrix (ECM) binding region (201-218) of rat insulin-like growth factor binding protein (IGFBP)-5 are important determinants in binding IGF-I", pp. 117-123

Lucic et al discloses that "mutants of IGFBP-2 with a higher affinity for IGF-II than [the] wild type might be difficult to elute with acid or by competition with IGF-II (p. 105 right col. l.24-27)." But there is no disclosure of inhibited release of IGF from an altered IGFBP-2 when an extracellular matrix (ECM) or protease is contacted.

Bramani et al indicates that the analogous IGFBP-5 has reduced IGF-I affinity when the former is ECM bound (end of the abstract). Contrary to this tendency, the instant invention reports an (altered) IGFBP that inhibits the release of IGF-I and IGF-II when contacting the ECM (p.3 l.15-31).

The said claims are therefore novel and inventive.

INDUSTRIAL APPLICABILITY (IA) Claims 1-39

While no unified criteria exist for determining what belongs in this category, there is nothing evident in the claims that would deprive them of affirmation in this category.